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parkell

510(k) SUMMARY

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Trade Name: Parkell TriPhasix Chromatic Alginate

Common Name: Alginate Impression Material

Classification Name: Impression Material (21 CFR §872.3660)

Equivalence: Chromaclone Color Changing Alginate
Orthalginate Impression Material
Algidento and Algiprint Impress Material
Dental Alginate Impression Material
Proof Alginate Impression Material
Cutter-Jel Alginate Impression Material

Description and Intended Use: TriPhasix Chromatic Alginate may be described as a vanilla flavored alginate impression which changes color from violet to pink to white to indicate completion of mixing, appropriate consistency for tray loading and appropriate consistency for impressioning, respectively. Slight alteration of water-to-powder ratios will deliver "heavy", "medium", or "light" body mixtures as preferred by the user. The product is intended for use as impression material as defined in §872.3660 of CFR 21, "to reproduce the structure of a patient's teeth and gums ... to provide models for study and for production of restorative prosthetic devices," etc.

The above-cited material complies with ISO 1563/1990 FOR ALGINATE. It contains no hazardous materials. Mixing time is 45 seconds. Total working time is 2 minutes 25 seconds. It is compatible with dental model gypsum and reproduces 50 micron detail.

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